DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Zubrin
Docket No.: 03E-0410

JUL - 8 2005

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,826,868, filed by Johnson & Johnson, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zubrin, the animal drug product claimed by the patent.

The total length of the regulatory review period for Zubrin is 2,347 days. Of this time, 1,887 days occurred during the testing phase and 460 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: October 28, 1996.

   The applicant claims October 29, 1996, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the INAD was October 28, 1996, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: December 27, 2001.

   The applicant claims December 20, 2001, as the date the new animal drug application (NADA) for Zubrin (NADA 141-193) was initially submitted. However, a review of FDA records reveals that NADA 141-193 was initially submitted on December 27, 2001.

3. The date the application was approved: March 31, 2003.

FDA has verified the applicant's claim that NADA 141-193 was approved on March 31, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Philip S. Johnson, Esq.
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